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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,392	12/07/2001	David Ganderton	478.1011	4915
23280	7590 04/26/2004		EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR			AZPURU, CARLOS A	
NEW YORK,		JK	ART UNIT	PAPER NUMBER
,			1615	12
			DATE MAILED: 04/26/2004	. 19

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
<u></u>	09/857,392	GANDERTON ET AL.
Office Action Summary	Examiner	Art Unit
	Carlos A. Azpuru	1615
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet wi	th the correspondence address
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, at 1 If NO period for reply is specified above, the maximum statutory perion Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	<ol> <li>In no event, however, may a reply within the statutory minimum of third will apply and will expire SIX (6) MON ute, cause the application to become AE</li> </ol>	eply be timely filed  y (30) days will be considered timely.  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).
Status		
<ul> <li>1) Responsive to communication(s) filed on 09</li> <li>2a) This action is FINAL. 2b) The 3 Since this application is in condition for allow closed in accordance with the practice under</li> </ul>	nis action is non-final.  vance except for formal matt	•
Disposition of Claims		
<ul> <li>4)  Claim(s) 1-11,19-23,25,26 and 29 is/are pen 4a) Of the above claim(s) is/are withdrest is/are allowed.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-9 is/are rejected.</li> <li>7)  Claim(s) 10-23,25,26 and 29 is/are objected s) Claim(s) are subject to restriction and</li> </ul>	rawn from consideration.	
Application Papers		
9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and according a deposition of the drawing sheet(s) including the correction of the deposition of	ccepted or b) objected to ne drawing(s) be held in abeyar ection is required if the drawing	ce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume  * See the attached detailed Office action for a list	nts have been received. nts have been received in A iority documents have been eau (PCT Rule 17.2(a)).	pplication No received in this National Stage
Attachment(s)		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date</li> </ol>	Paper No(s	ummary (PTO-413) )/Mail Date Iformal Patent Application (PTO-152) 

Art Unit: 1615

## **DETAILED ACTION**

Receipt is acknowledged of the extension of time and amendment filed 02/09/03.

Applicant is requested to amend the specification by adding a sentence at the beginning of the specification indicating the priority claim, and status of that case.

The rejection under 35 USC 103 over Kuo et al is hereby withdrawn.

The following are new rejections are cited in view of an updated search:

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the use of the word "sample". The claim fails to set out the sample size or proportion. Clarification is requested.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/32096 (WO'096).

WO'096 discloses particles used for drug delivery comprising various amino acids such as leucine (see page 9, lines 3-17). The particles may be spray dried, with in let and outlet temperatures as described at page 19, lines 18-21. Diameter is less than 5.2 um, with particles of less than 5 um disclosed for deep lung delivery. Thickness would inherently also be within the claimed parameters in order to achieve this delivery. Further, as in the examples given in the instant application, WO'096 uses spray drying with the same inlet and outlet temperature parameters. Since diameter and size are also within the claimed parameters, bulk density (a function of mass/volume) would also be inherent. The instant claims re anticipated by WO'096.

Claims 10-23, 25, 26, and 29 are objected to as dependent upon rejected base claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0602. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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